

REMARKS

Claim Objections

Claim 34 is objected to under 37 C.F.R. §1.75(c) as allegedly being improperly dependent for failing to further limit the subject matter of the independent claim (33) from which it depends. Claim 33 requires that the intraocular lens manufactured in accordance with the method thereof “has an equilibrium water concentration less than about 10 weight percent,....” Claim 34 requires that “the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%.” In accordance with the Office Action claim 34 is alleged to not be limiting of claim 33. This is not believed to be correct. Claim 33 in accordance with its own language specifies a nominal equilibrium water concentration. In contrast, claim 34 requires a differential between the “rigid intraocular lens” and the “foldable hydrated intraocular lens.” It is believed that claim 34 limits the structure of claim 33 in that a differential is included in claim 34 whereas no relative value is specified in broader claim 33. It follows from the above that claim 34 does properly depend from claim 33 and that this objection should be withdrawn.

Prior art rejections: Rejection under 35 U.S.C. §102

Claims 33, 34 and 37 are rejected as allegedly being anticipated (35 U.S.C. §103(b)) by U.S. 4, 731, 079 (“Stoy”). This rejection is respectfully traversed.

Stoy is analyzed in detail in the full paragraph on page 3 of the Office Action. The Office Action has ignored a critical distinction between the material described in Example II of Stoy and the material of claims 33, 34, and 37. The Office Action has also erroneously equated a cross-linker and a hydrogel in the analysis of the disclosure of Example II of Stoy. Specifically, glass transition temperature (T_g) was not measured at all in Example II. At column 14 line 58 it is stated in the Office Action that “ T_s was 25.5°C.” “ T_s ” is defined as

“The softening temperature at which the polymer may be readily deformed but at or above which it will readily return to its shape upon release of the deforming force. T_d is the temperature above which the polymer will be permanently deformed and damaged. The designation of T_s and T_d as definite temperatures is inexact for most polymers. The effect takes place within about plus or minus 3°C of a designated temperature,” (column 4 line 15).

It is noted further in Stoy at column 6 line 54 that:

“ T_s may correspond to glass-transition temperature T_g which has a well-known and well-defined meaning. In some cases however, T_s and T_g are not identical *i.e.* in cases of two phase polymeric systems or the dual character of interaction between polymer chains.”

In other words T_g is not used at all in Example II, it is the unknown and self-defined, potentially unrelated, T_s .

There is a further reason that the compound polymerized in step “A” of claim 33 is not anticipated nor rendered obvious by Stoy. The third material of Stoy Example II, *viz.*, tetraethyleneglycol-bismethacrylate is not “a high water content hydrogel-forming monomer” as is alleged in the Office Action. Tetraethyleneglycol-bis-methacrylate (col. 14, line 52) is, in fact, a cross-linking agent. It is not a high water content, hydrogel-forming monomer as is suggested in the Office Action. In essence, Stoy *et al.* neither anticipates nor renders obvious the present invention given its complete failure to recognize the advantages of having a significant amount of hydrogel-forming monomer present in the IOL polymer.

It is to be conceded that Stoy does, in fact, discuss a need for hydration. However, the discussion spanning column 10 line 18 actually teaches away from the present invention in that only “surface hydration” is described. As is noted at column 10 line 39:

“The permanent hydrogel layer can be made by surface hydrophilization by some of the methods which are well known in the art for various polymers. The surface hydrophilization can be based on oxidation, hydrolysis, transesterification and the like. As long as the swelling gradient thus formed is regular, the optical properties of the IOL do not deteriorate and the optical quality is rather insensitive to the thickness of the hydrophilic layer....”

No hint or suggestion that a terpolymer including a hydrogel-forming monomer be polymerized into the bulk of the polymer material is contained in Stoy. In other words, Stoy actually teaches away from the present invention by suggesting that high levels of hydrogel-forming monomer tend to cause the optical properties of the IOL to “deteriorate.”

It follows from the above that Stoy does not anticipate claims 33, 34 and 37.

Obviousness rejection 35 U.S.C. §103

Claim 35 has been rejected as being anticipated by or obvious over Stoy. Claim 35 depends from claim 33. Claim 33 has not been rejected as obvious over Stoy. By definition

claim 35 is narrower than claim 33 (37 C.F.R. §1.75). It follows that if claim 33 is not obvious from Stoy, neither can claim 35 be obvious over Stoy.

Claim 35 states that the intraocular lens is a "20 diopter lens and has a central thickness less than about 0.4 mm."

At the bottom of page 4 of the Office Action it is stated that

"[The] polymers of Stoy are essentially the same as instantly claimed, and they are made via essentially the same method as instantly claimed,...."

As is noted above the polymers of the present invention are not "essentially the same as" those disclosed by Stoy. Stoy neither discloses nor suggests the use of a high water content hydrogel-forming monomer as in the present polymers. Nothing in Stoy *et al.* suggests using anything other than very small amounts of a cross-linker. Thus, Stoy cannot and does not render obvious claim 35.

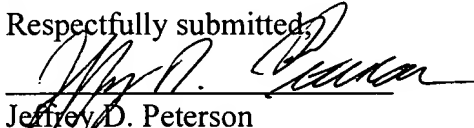
Claim 36 also stands rejected over Stoy under §103. Claim 36 also depends from claim 33. For the reasons set forth above this obviousness rejection is believed to be incorrect and should be withdrawn.

Claim 36 is a dependent method claim which has specific times and temperatures at which polymers of the present invention are hydrated. Absolutely none of those limitations are remotely suggested or set forth in Stoy.

Moreover, the examiner seems to presume that neither the order of performing the steps, the steps themselves, the temperature, nor the times are important to overall process success. Clearly, Stoy *et al.* cannot and does not anticipate nor render obvious anything in claim 36 given its complete absence of disclosure relevant to the claimed invention.

For the reasons set forth above, applicants respectfully request withdrawal of the present rejections and passage of all pending claims in this application to issue.

Respectfully submitted,


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